

5774-01-MJA
Application No. 09/674,819

REMARKS

I. Status of the Application

This paper responds to a Final Office Action which was mailed on November 1, 2006. As originally filed, the application included claims 1-17. In response to a Restriction Requirement mailed August 29, 2001, Applicant amended claims 1 and 12 and added claims 18 and 19. In response to an Office Action mailed February 6, 2002, which rejected all of the claims, Applicant amended claim 12, canceled claims 18 and 19, and added claims 20 and 21. A subsequent Final Office Action, which was mailed on November 1, 2002, maintained the rejection of claims 1-17, and rejected newly added claims 20 and 21. Applicant subsequently filed an RCE. In the submission that accompanied the RCE, Applicant amended claims 1-17, 20, and 21, and added claims 22-27. In response to an Office action mailed September 26, 2003, Applicant canceled claims 1-17 and 20-27 and added new claims 28-42. The case was transferred to a new Art Unit. Applicant subsequently responded to a Restriction Requirement/Election of Species mailed February 8, 2005. In response to a Final Office Action mailed June 2, 2005, Applicant amended claims 28 and 40, and filed an RCE. In response to an Office Action, which was mailed on January 26, 2006, Applicant amended claims 28, 35, 37, and 41, and added claim 43. A subsequent Final Office Action, which was mailed November 1, 2006, rejected all of the pending claims. This paper amends claims 28 and 41 and provides an argument against the current rejections. Accordingly, claims 28, 35-37, 40-41 and 43 are currently under consideration in this application.

Applicant submits that entry of this after final amendment is proper because the amendment raises no new issues requiring a further search of the prior art and it places the claims in condition for allowance. Applicant respectfully requests entry of the after final amendment and reconsideration of the pending claims.

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II. Rejection of Claims Under 35 U.S.C. §102(a) and §103(a)

The Final Office Action rejected all of the pending claims under §102(a) and §103(a) as anticipated by or in view of Schrier. Applicant asserts that the claims are not anticipated by, or obvious, in view of Schrier.

Anticipation requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently. This invention provides a stabilized solid composition, which is characterized by the combination of a 4-amino-3-substituted butanoic acid derivative selected from gabapentin or pregabalin and propylene glycol as a stabilizing agent for the 4-amino-3-substituted butanoic acid derivatives. Schrier does not expressly disclose stabilized solid compositions or methods for stabilizing such compositions which comprise gabapentin or pregabalin and propylene glycol. Instead, Schrier provides a generic listing of compatible and suitable pharmaceutical carriers and diluents, including gelatin capsules, sugars, starches, cellulose derivatives, gelatin, glidants, vegetable oils, glycols, sweeteners, buffers, water, preservatives, coloring agents, and flavoring agents that may be used in a pharmaceutical formulation. However, none of the specific formulations described in Schrier contain propylene glycol. Therefore, applicant submits that Schrier does not anticipate claims 28, 35-37, 40-41, and 43.

Furthermore, Schrier does not render the claims obvious. Schrier does not even hint that propylene glycol will stabilize gabapentin, pregabalin, or similar 4-amino-3-substituted butanoic acid derivatives. Rather, as noted above, Schrier only provides a general listing of pharmaceutical carriers and diluents that may be used in pharmaceutical formulations. These carriers and diluents belong to different functional categories of substances. Thus, at most, Schrier represents an obvious to try rationale, which cannot render the claims obvious.

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Schrier does not exemplify the preparation of any solid compositions of a 4-methyl-3-substituted butanoic acid derivative. Schrier provides examples of preparing liquid solutions or suspensions of gabapentin and pregabalin in a vehicle of hydroxypropylmethylcellulose and Tween80 for oral dosing or dissolved in an artificial cerebral spinal fluid for injection (see Examples 1-4 in Schrier). Applicant respectfully submits that nothing in Schrier would motivate a skilled artisan to use propylene glycol to block the chemically induced degradation of the 4-amino-3-substituted butanoic acid derivatives in the preparation of a stable and solid pharmaceutical composition. Therefore, the teachings of Schrier do not render the composition of the instant claims obvious.

As described on pages 3 and 4 of the specification, pharmaceutical preparations containing gabapentin or similar 4-amino-3-substituted butanoic acid derivatives are difficult to prepare because the active ingredient may undergo degradation. Under sealed conditions, gabapentin degradation is decreased by at least 35% when gabapentin is formulated with propylene glycol (reconstructed in part from Table 3, page 52 of the specification):

Storage Conditions	Water	Propylene Glycol	%
Initial	0.003	0.003	0
60°C/1 week (sealed)	0.017	0.011	35.3
60°C/2 weeks (sealed)	0.020	0.013	35.0

These stabilizations are completely unexpected, and therefore, Applicant respectfully submits the claims are patentable.

III. Conclusion

In view of the foregoing, Applicant submits that independent claims 28 and 41 are in condition for allowance, and as such, dependent claims 35-37, 40, and 43 are also in condition for allowance. Applicant respectfully requests that the rejections be withdrawn.

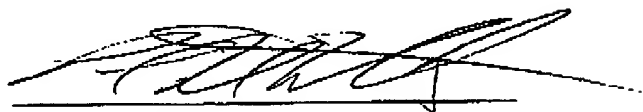
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Applicant believes that there are no fees associated with the filing of the present amendment. However, if any fees are required in connection with the filing of this paper, the Commissioner is hereby authorized to charge deposit account number 23-0455 for any appropriate charges.

Respectfully submitted,

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